DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 31, 2015

Zimmer, Incorporated
Mr. Stephen H. McKelvey
Senior Project Manager, Trauma Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581

Re: K143165
Trade/Device Name: Herbert/Whipple® Bone Screw System, Herbert™ Bone Screw, Herbert™ Cannulated Bone Screw System, and Herbert™ Mini Bone Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: February 27, 2014
Received: March 2, 2015

Dear Mr. McKelvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143165

Device Name

Herbert/Whipple® Bone Screw System, Herbert™ Bone Screw, Herbert™ Cannulated Bone Screw System, and Herbert™ Mini Bone Screw

Indications for Use *(Describe)*

The Herbert™ Mini Bone Screw (2.5mm diameter, non-cannulated) and the Herbert™ Bone Screw (3.0mm diameter, non-cannulated) are indicated for fixation of intra-articular and extra-articular fractures, avulsions, non-union, and osteotomies of small bones and small bone fragments; as well as arthrodeses of small joints.

The Herbert/Whipple® Bone Screw System (3.0mm diameter, cannulated) are indicated for the fixation of fractures and non-unions of small bones and small bone arthrodeses, including, but not limited to, scaphoid fractures; intra-articular fractures of the tarsals, metatarsals, carpals and metacarpals; bunionectomies and osteotomies; arthrodeses of small joints (e.g. phalanges); fractures of the patella, ulna and radial styloid.

The Herbert™ Cannulated Bone Screw System (4.5mm and 6.5mm diameter) are indicated for fracture fixation, reconstruction, osteotomy, and arthrodesis of various bones and bone fragments including joint fusions (arthrodeses) in the foot and fixation of intra-articular fractures of the humerus, femur and tibia.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

510(k) Summary

Sponsor:

Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Contact Person:

Stephen H. McKelvey, MA, RAC
Senior Project Manager, Regulatory Affairs
Telephone: 574-372-4944
Fax: (574) 372-4605

Date:

October 30, 2014

Trade Name:

Herbert/Whipple Bone Screw System
Herbert Bone Screw
Herbert Cannulated Bone Screw System
Herbert Mini Bone Screw

Common Name:

Screw, Fixation, Bone

Classification Names and References:

Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040, HWC)

Classification Panel:

Orthopedics/87

Predicate Device(s):

Synthes 1.5mm Headless Compression Screws, manufactured by Synthes, K090949, cleared July 31, 2009, Synthes 2.4mm Headless Compression Screws, manufactured by Synthes, K021556, cleared August 9, 2002, Synthes 4.5mm and 6.5mm Headless Compression Screws, manufactured by Synthes, K080943, cleared April 23, 2008.

Purpose and Device Description:

The *Herbert* devices are cannulated and non-cannulated variable pitch screws that are headless, threaded at both ends and are made from *Tivanium*® Ti-6Al-4V Alloy. *Herbert* screws are designed to provide rigid fixation for various fractures.

Intended Use:

The *Herbert*™ Mini Bone Screw (2.5mm diameter, non-cannulated) and the *Herbert*™ Bone Screw (3.0mm diameter, non-cannulated) are indicated for fixation of intra-articular and extra-articular fractures, avulsions, non-union, and osteotomies of small bones and small bone fragments; as well as arthrodeses of small joints.

The *Herbert/Whipple*® Bone Screw System (3.0mm diameter, cannulated) are indicated for the fixation of fractures and non-unions of small bones and small bone arthrodeses, including, but not limited to, scaphoid fractures; intra-articular fractures of the tarsals, metatarsals, carpals and metacarpals; bunionectomies and osteotomies; arthrodeses of small joints (e.g. phalanges); fractures of the patella, ulna and radial styloid.

The *Herbert*™ Cannulated Bone Screw System (4.5mm and 6.5mm diameter) are indicated for fracture fixation, reconstruction, osteotomy, and arthrodesis of various bones and bone fragments including joint fusions (arthrodeses) in the foot and fixation of intra-articular fractures of the humerus, femur and tibia.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

- **Shelf Life -** Accelerated aging testing conducted shows that the sterile devices included in this submission have a shelf life of 10 years.

- **Biocompatibility** – Biocompatibility testing of the subject devices was conducted per ISO 10993-1 and Good Laboratory Practices (21 CFR 58). All testing passed.

- **Performance Evaluation** – The engineering analyses demonstrated the estimated axial pull out force, maximum torque to failure, and static bending moment of the *Herbert* devices met the predetermined requirements established for mechanical performance.

  Zimmer also conducted insertion torque and removal torque testing for each of the subject devices and compared the results to the maximum torque-to-failure. In all cases, the insertion and removal torques

were significantly less than the torque-to-failure for the screws, indicating that each of the subject screws can be inserted and removed during surgery without screw failure.

Conclusions: The data presented in this submission show that the changes do not affect the safety and/or effectiveness of the subject devices and that the subject devices will perform in a substantially equivalent manner to the predicate devices.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for these devices to show substantial equivalence.